

level for three of the nutrients per labeled serving size.

[59 FR 24228, May 10, 1994, as amended at 60 FR 217, Jan. 3, 1995; 63 FR 7281, Feb. 13, 1998; 64 FR 72492, Dec. 28, 1999; 68 FR 463, Jan. 6, 2003]

§§ 381.464–381.468 [Reserved]

§ 381.469 Labeling applications for nutrient content claims.

(a) This section pertains to labeling applications for claims, express or implied, that characterize the level of any nutrient required to be on the label or in labeling of product by this subpart.

(b) Labeling applications included in this section are:

(1) Labeling applications for a new (heretofore unauthorized) nutrient content claim,

(2) Labeling applications for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient, and

(3) Labeling applications for the use of an implied claim in a brand name.

(c) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(d) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies accompany a labeling application, the applicant shall include, with respect to each nonclinical study included with the application, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in part 58 of chapter 1, title 21, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations accompany a labeling application, the applicant shall include, with respect to each clinical investigation included with the application, either a statement that the investigation was conducted in compliance with the requirements for institutional review set forth in part 56 of chapter 1, title 21, or was not subject to such requirements in accordance with § 56.194 or § 56.105, and that it was conducted in compliance with the requirements for informed consents set forth in part 50 of chapter 1, title 21.

(g) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(h) The data specified under this section to accompany a labeling application shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(i) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(j) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(k)(1) Labeling applications for a new nutrient content claim shall be accompanied by the following data which shall be submitted in the following

form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date) _____

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the claim and its proposed use).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the nutrient content claim and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement shall address why the use of the term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify the level at which the nutrient must be present or what other conditions concerning the product must be met for the appropriate use of the term in labels or labeling, as well as any factors that would make the use of the term inappropriate.

(ii) A detailed explanation supported by any necessary data of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, and scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

(iii) Analytical data that demonstrates the amount of the nutrient that is present in the products for which the claim is intended. The assays should be performed on representative samples in accordance with 381.409(h). If no USDA or AOAC methods are available, the applicant shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data shall include a statistical analysis of the analytical and product variability.

(iv) A detailed analysis of the potential effect of the use of the proposed claim on food consumption, and any corresponding changes in nutrient intake. The analysis shall spe-

cifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the above analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,

Applicant _____

By _____
(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the

complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the FEDERAL REGISTER a proposed rule to amend the regulations to authorize the use of the nutrient content claim. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed nutrient content claim shall be approved for use on the labeling of poultry products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(A) If the applicant fails to accept the determination of the Adminis-

trator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the FEDERAL REGISTER a final rule amending the regulations to authorize the use of the claim.

(1)(1) Labeling applications for a synonymous term shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date) _____

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under subpart Y of part 381).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the synonymous term, the existing term defined by a regulation with which the synonymous term is claimed to be consistent, and the nutrient that the term is intended to characterize the level of. The statement shall address why the use of the synonymous term as proposed will

not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

(ii) A detailed explanation supported by any necessary data of why use of the proposed term is requested, including whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed synonymous term is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to

the merits or validity of the Administrator's decision to deny the use of the proposed synonymous term.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the claim is approved, the Agency shall notify the applicant, in writing, and shall publish in the FEDERAL REGISTER a notice informing the public that the synonymous term has been approved for use.

(m)(1) Labeling applications for the use of an implied nutrient content claim in a brand name shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date) _____

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the implied nutrient content claim, the nutrient the claim

is intended to characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation, and the brand name of which the implied claim is intended to be a part. The statement shall address why the use of the brand-name as proposed will not be misleading. The statement shall provide examples of the types of products on which the brand name will appear. It shall also include data showing that the actual level of the nutrient in the food would qualify the label of the product to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient shall meet the requirements stated under labeling application format in paragraph (k)(1)(iii) of this section.

(ii) A detailed explanation supported by any necessary data of why use of the proposed brand name is requested. This explanation shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group and scientific data sufficient for such purpose.

Yours very truly,

Applicant _____

By _____

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed implied nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing

with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish a notice of the labeling application in the FEDERAL REGISTER seeking a comment on the use of the implied nutrient content claim. The notice shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's notice shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the implied nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the implied nutrient content claim shall be approved for use on the labeling of poultry products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason

why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the FEDERAL REGISTER a notice informing the public that the implied nutrient content claim has been approved for use.

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583-0088.)

[58 FR 675, Jan. 6, 1993, as amended at 59 FR 45198, Sept. 1, 1994; 60 FR 217, Jan. 3, 1995]

§§ 381.470-381.479 [Reserved]

§ 381.480 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any product that purports to be or is represented for special dietary use because of usefulness in reducing body weight shall bear:

(1) Nutrition labeling in conformity with § 381.409 of this subpart, unless exempt under that section, and

(2) A conspicuous statement of the basis upon which the product claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any product subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary product may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the product under the applicable law and regulations of this chapter. Any product that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener; e.g., "Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s)."

(c) *"Low calorie" foods.* A product purporting to be "low calorie" must comply with the criteria set forth for such foods in § 381.460.

(d) *"Reduced calorie" foods and other comparative claims.* A product purporting to be "reduced calorie" or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such foods in § 387.460(b) (4) and (5).